



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1635]

Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief." This draft guidance describes circumstances under which an applicant may be eligible for a barrier-to-innovation waiver for some new drug applications (NDAs) for fixed-combination versions and single-entity versions of previously approved antiretroviral therapies for the treatment of human immunodeficiency virus (HIV).

DATES: Submit either electronic or written comments on the guidance [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-1635 for "Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the

President's Emergency Plan for AIDS Relief.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket

number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ted Palat, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2185, Silver Spring, MD 20993, 240-402-8739, Ted.Palat@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President’s Emergency Plan for AIDS Relief.” The draft guidance describes the circumstances under which certain applications for fixed-combination and single-entity versions of previously approved antiretroviral therapies for the treatment of HIV under the President’s Emergency Plan for AIDS Relief (PEPFAR) may be eligible for a barrier-to-innovation waiver.

In October 2006, to encourage applicants to submit applications for HIV combination therapies that can be used in PEPFAR, FDA issued a final guidance entitled “Fixed Dose

Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV” (fixed-combination guidance). Attachments to the fixed-combination guidance describe some scenarios for approval of fixed-combination for the treatment of HIV and provide examples of drug combinations considered acceptable as fixed combinations and examples of those not considered acceptable as fixed combinations. Although the 2006 fixed-combination guidance focuses on fixed combinations, the scientific principles outlined in the guidance also apply to single ingredient versions of antiretroviral drugs that are components of regimens listed in Attachment B. The guidance also explains that the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides for certain circumstances in which FDA may grant a waiver or reduction in user fees.

This draft guidance is a revision of the guidance for industry entitled “User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR,” issued February 2007. In this guidance, FDA provides information about the circumstances under which certain applications for fixed-combination and single-entity versions of previously approved antiretroviral therapies for the treatment of HIV under PEPFAR may be eligible for a barrier-to-innovation waiver.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President’s Emergency Plan for AIDS Relief.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The burden of information collection associated with requesting waivers of user fees (including PEPFAR waivers) was previously approved under OMB control number 0910-0693. The burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) is not included in this analysis as the burden is already approved under OMB control number 0910-0297. The collections of information associated with submission of a new drug application or biologics license application are approved under OMB control numbers 0910-0001 and 0910-0338, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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